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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,440	09/08/2003	Kazumasa Masuda	KITO3.001AUS	1430

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EXAMINER	
HALL, DEANNA K	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
02/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/657,440	MASUDA ET AL.	
	Examiner	Art Unit	
	DEANNA K. HALL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-8,11 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8,11 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/09 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 12/17/09.

3. In the reply, the applicant amended claims 1, 5-8, 11, 17; canceled claims 14-16; added new claims 18-21. Claims 1-2, 5-8, 11, 17-21 are pending in the application.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1-2, 5-8, 11, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al. (US 5,840,026) ("Uber").**

The following claim limitations are disclosed in the aforementioned Uber patent in Figures 2, 3a and 3b, Table I, C2 L66- C3 L28 and C5 L21-C8 L62.

Uber discloses:

(claims 1, 8) A liquid injection mechanism and method for injecting a contrast medium into a subject; pattern storing means for registering data of a variable pattern in which an injection rate of the contrast medium for keeping an image contrast of the fluoroscopic image within a predetermined range varies with time, said pattern storing means storing registered data in which the variable pattern is comprised of a linear decrease of the injection rate of the contrast medium from the start of injection to a set point of time, and from said point of time a constant or a linear increase of the injection rate of the contrast medium within a predetermined injection time; and rate controlling means for varying an operating speed of said liquid injection mechanism according to a modified variable pattern, said modified variable pattern obtained by vertically moving said variable pattern depending on a total amount of the contrast medium to be injected into the subject with said predetermined injection time unchanged. Said modified variable pattern varying an operating speed of a liquid injection mechanism with time.

Pattern storing means comprises means for registering the data of the variable pattern in order to maintain a state in which the image contrast of the fluoroscopic image that is produced by said contrast medium approximates an optimum level.

Coefficient storing means for registering data of predetermined coefficients

assigned to respective regions to be imaged of the subject; data entering means for accepting entered data of a region to be imaged of the subject; coefficient reading means for reading the data of one of the coefficients from said coefficient storing means depending on the region to be imaged of the subject whose data has been entered by said data entering means; and total calculating means for calculating said total amount of the contrast medium to be injected into the subject based on said concentration whose data has been read by said concentration reading means.

The contrast medium is available in a plurality of types having different concentrations of an effective component contained therein, further comprising: concentration storing means for registering data of the different concentrations in the types of said contract medium; coefficient storing means for registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; data entering means for accepting entered data of a type of the contrast medium; concentration reading means for reading data of the concentration from said concentration storing means depending on the type of the contrast medium whose data has been entered by said data entering means; coefficient reading means for reading the data of one of the coefficients from said coefficient storing means depending on the region to be imaged of the subject whose data has been entered by said data entering means; and total calculating means for calculating said total amount of the contrast medium to be injected into the subject based on said body weight obtained by said data entering means, said concentration obtained by said concentration reading means, and said coefficients obtained by said coefficient reading means.

Uber further discloses a computer unit comprising: pattern storing means for registering data of a variable pattern in which an injection rate of the contrast medium varies with time, said pattern storing means storing registered data in which the variable pattern is comprised of a linear decrease of the injection rate of the contrast medium from the start of injection to a set point of time, and from said point of time a constant or a linear increase of the injection rate of the contrast medium within a predetermined injection time; and rate controlling means for varying an operating speed of said liquid injection mechanism according to a modified variable pattern, said modified variable pattern obtained by vertically moving said variable pattern depending on a total amount of the contrast medium to be injected into the subject with said predetermined injection time unchanged.

A computer readable medium having a program stored thereon for executing a computer to perform a method according to independent claim 8.

Registering data of the different concentrations in the types of said contrast medium; coefficient storing means for registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; data entering means for accepting entered data of at least the body weight of the subject, a region to be imaged of the subject, and one of the types of the contrast medium; concentration reading means for reading data of the concentration from said concentration storing means depending on the type of the contrast medium whose data has been entered by said data entering means; coefficient reading means for reading the data of one of the coefficients from said coefficient storing means depending on the region to be imaged of

the subject whose data has been entered by said data entering means; and total calculating means for calculating said total amount of the contrast medium to be injected into the subject based on body weight, concentration, and said coefficient.

Concentration storing means for registering data of the different concentrations in the types of said contract medium; coefficient storing means for registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; data entering means for accepting entered data of at least the body weight of the subject, a region to be imaged of the subject, and one of the types of the contrast medium; concentration reading means for reading data of the concentration from said concentration storing means depending on the type of the contrast medium whose data has been entered by said data entering means; coefficient reading means for reading the data of one of the coefficients from said coefficient storing means depending on the region to be imaged of the subject whose data has been entered by said data entering means; and total calculating means for calculating said total amount of the contrast medium to be injected into the subject based on said body weight whose data has been entered by said data entering means, said concentration whose data has been read by said concentration means and said coefficient whose data has been read by said coefficient reading means.

Further, the disclosure of Uber would make the claimed specific pattern of the injection rate recited in claims 1, 8 and 11 obvious to try. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known

options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR International Co., v. Teleflex Inc. et al.* 127 U.S. 1727, 1742(2007). Further, the initial linear decrease of the injection rate up to a set point of time followed by a constant or a linear increase of the injection rate of the contrast medium is obvious to try in order to achieve decrease waste and cost while increasing efficiency, Uber C1 L4-13.

In addition, the specific pattern of the injection rate recited in claims 1, 8 and 11 is considered optimization through routine experimentation of a result-effective variable. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Further, "a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In Uber, the particular injection profile selected by the system is designed to provide the best image quality for the particular patient C3 L25-28. Thus, Uber is optimizing the result-effective variable, image quality (CT value). An electronic interface 56, not merely subjective personal satisfaction of the user, allows for automatic adjustment of the system C6 L29-31. Therefore, the determination of the optimum ranges for the injection pattern based on the image quality are properly

characterized as obvious subject matter characterized by routine experimentation by those of ordinary skill in the art.

Response to Arguments

6. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that "as the injection time is determined by the injection rate and volume, it is appear that Uber does disclose or suggest altering the injection time as a whole". This argument is not persuasive. Injection rates and volumes can be modified without a change to the overall injection time. Examiner maintains that Uber, throughout the specification, discloses the system as adjusting the concentration of the contrast media or the flow rate to provide a desirable image C11 L59-67. No where in the specification does Uber disclose or even suggest altering the injection time as a whole. Extending the injection time as a whole would cause discomfort to the patient, thus, as in Uber other means such as adjusting concentrations or flow rates, are utilized to provide the best image qualilty. Thus, the examiner maintains that by experimentation and optimization as discussed above, the waveform or the variable pattern is vertically moved with the injection time unchanged as the amended claims recite.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/
Examiner, Art Unit 3767
2/4/10

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767